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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/823,294 | 04/12/2004 | Kent Voorhees | 022116.0102PTUS | 4536 |

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PATTON BOGGS
1660 LINCOLN ST
SUITE 2050
DENVER, CO 80264

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
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1648

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 31 DAYS | 01/09/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/823,294

Applicant(s)

VOORHEES ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-114 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-79, 84-86, and 95-99, drawn to methods for the detection of a microorganism in a sample comprising the use of a bacteriophage, classified in class 435, subclass 5.
 - II. Claims 80-83, drawn to methods for determining the resistance/susceptibility of a microorganism to antibiotics, classified in class 435, subclass 29.
 - III. Claims 87-91, drawn to methods for manufacturing a lateral flow test substrate, classified in class 435, subclass 283.1.
 - IV. Claims 92-94, drawn to methods for manufacturing a SILAS test substrate, classified in class 435, subclass 283.1.
 - V. Claims 100-107, drawn to an apparatus for detecting a microorganism, classified in class 435, subclass 287.1.
 - VI. Claims 108-114, drawn to kits for the detection of a microorganism, classified in class 435, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions related to methods having different effects (Group I is a detection methods, Group II is a method

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of determining drug susceptibility, and Groups III and III are drawn to methods of making different types of substrates), and different modes of operation. The inventions are therefore unrelated and distinct.

3. The inventions of Groups V and VI are related as products and process of use with the method of Groups I and II. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the claimed products may be used in either of the methods of Groups I or II, and is therefore distinct from either of them.

4. The inventions of Groups V and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs in that the kit comprises a phage and a buffer and the apparatus comprises a substrate and a color moderator. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. While the inventions may be used together, they are also independently useful.

5. The inventions of Groups II and III are related as process of making and product made with the products of Group V and VI. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and

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materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed products may be made through use of different processes. For example, the substrates may be made through the use of molds into which the components are mixed or added so as to avoid the necessity of cutting, or to apply the biological materials in other forms than lines. Also, the optical coatings may be attached to, rather than formed on, the provided substrate. The claimed products are therefore distinct from the claimed methods of making them.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following patentably distinct species:

For Group I above, the Applicant is required to elect

One method of assaying from (a) the use of a lateral flow device (claim 4), (b) complexing with color beads (claims 5), (c) antibody attachment (claim 6), (d) SILAS (claims 8 and 9), (e) mass spectrometry (claims 10-12), and (f) the use of a laser beam (claim 13).

If species (e) is elected the applicant must elect either MALDI, the use of magnetic beads, or both.

One of the modes of detection from (A) using the presence of the phage or phage substance to determine the presence of the bacteria, (B) using a comparison of the presence of

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the phage or phage substance with a control (claim 49), or (C) detecting a color change to determine the presence of a bacteria (claims 84-86).

One of the methods of lysing the bacteria from those identified in claims 3 (and 15), claim 16, or one of the modes identified in claim 17.

One of the methods of dissociating the phage from those identified in (e.g.) claim 20.

One of the methods of tagging the parent phage selected from biotinylation, or attachment to a substrate.

One of the modes of genetically engineering the bacteriophage selected from those identified in claims 33-36.

For each of Groups II, V, and VI, the Applicant is required to elect a species wherein the claimed invention involves (a) lateral flow or (b) SILAS.

The species are independent or distinct because:

For species (a) –(f) and (A)-(C), the modes of lysing the bacteria, of dissociating the phage, of tagging the parent phage, and of engineering the bacteriophage of Group I, and the species of Groups II, V, and VI, these species are drawn to related inventions, which are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs and

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modes of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Further, the subspecies of (e) are related as combination and subcombinations. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of either of subcombination as claimed as it may rely on either or on both for patentability. The subcombinations each have separate utility in detection methods.

It is also noted the species (e) and (f) are also related as subcombinations usable together (e.g. in MALDI-TOF-MS). However, as they may also be used independently, and as they do not appear to be obvious variants of each other, the species are distinct.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for Group I, claim 80 for Group II, claim 100 for Group III, and claim 108 for Group VI.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

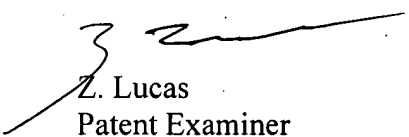
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Z. Lucas
Patent Examiner